II. Remarks

A. Status of the Claims

Claims 13-24 will be currently pending after entry of this amendment. Claims 1-12 and 25-56 have been cancelled without prejudice as they do not read on the elected invention. Claims 18, 19 and 22 are withdrawn without prejudice, as they do not read on the elected species. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

B. Claims Restrictions Under 35 U.S.C. § 121

1. Restriction

In the Office Action, claims 1-56 were restricted under 35 U.S.C. §121 to the following distinct inventions:

I. Claims 1-12, drawn to a pharmaceutical dosage form comprising an immediate release component and controlled release component exhibiting an in vitro dissolution profile in simulated intestinal fluid medium comprising at least 80% $GABA_B$ agonist release after 1 hour for the immediate release component and at least 5% $GABA_B$ agonist release after 1 hour, at least 20% $GABA_B$ agonist release after 4 hours and at least 30% $GABA_B$ agonist release after 6 hours for the controlled release component, classified in class 424, subclass 457.

II. Claims 13-24, drawn to a pharmaceutical dosage form comprising an immediate release component and controlled release component exhibiting an in vitro dissolution profile in simulated gastric fluid/simulated intestinal fluid medium (1 hour switchover) comprising at least 80% $GABA_B$ agonist release after 1 hour for the immediate release component and from about 2% to about 90% $GABA_B$ agonist release after 1 hour, at least 30% $GABA_B$ agonist release after 4 hours and at least 40% $GABA_B$ agonist release after 6 hours for the controlled release component, classified in class 424, subclass 457.

III. Claims 25-40, drawn to a pharmaceutical dosage form comprising an immediate release component and controlled release component exhibiting an in vivo plasma profile comprising a mean maximum $GABA_B$ agonist release from about 30 minutes to about 7 hours after administration to a fasting patient, classified in class 424, subclass 457.

IV. Claims 41-56, drawn to a pharmaceutical dosage form comprising an immediate release and controlled release component exhibiting an in vivo plasma profile comprising at least 2 hours of sustained $GABA_B$ agonist concentrations at greater than therapeutic levels, after 2 hours following administration to a fasting patient, classified in class 424, subclass 457.

In response, Applicants elect, without traverse, the claims of Group II, i.e., claims 13-24, drawn to a pharmaceutical dosage form comprising an immediate release component and controlled release component exhibiting an in vitro dissolution profile in simulated gastric fluid/simulated intestinal fluid medium (1 hour switchover) comprising at least 80% $GABA_B$ agonist release after 1 hour for the immediate release component and from about 2% to about 90% $GABA_B$ agonist release after 1 hour, at least 30% $GABA_B$ agonist release after 4 hours and at least 40% $GABA_B$ agonist release after 6 hours for the controlled release component. Claims 1-12 and 25-56 have been canceled without prejudice as they do not read on the elected invention.

2. Species Election

In the Office Action, the claimed were restricted to the following species:

Species I - Baclofen optical isomer composition

a) Racemic mixture of baclofen

b) Essentially of the L-baclofen enantiomer

c) At least about 95% of the L-baclofen enantiomer

Species II - Dosage form

a) tablet

b) capsule

In response, Applicants elect, without traverse:

Species I: a) a racemic mixture of baclofen; and

Species II: b) a capsule as the dosage form.

Claims 18, 19 and 22 have been withdrawn without prejudice as they do not read on the elected species.

III. Conclusion

An early and favorable action on the merits is earnestly solicited. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is invited to telephone the undersigned at (973)597-6162. The undersigned also may be contacted via e-mail at epietrowski@lowenstein.com. All correspondence should be directed to our address listed below.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Deposit Account No. 50-1358.

Respectfully submitted,
Lowenstein Sandler PC

Date: October 30, 2007

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